Defendant J&J can claim that Plaintiffs failed to establish the particular circumstances of J&J's fraud.

The SICOR Group ("SICOR") laments that Plaintiffs failed to identify a SICOR "brand name" drug. SICOR Mtn. at 3. What SICOR ***does not*** address are the MCC's particularized allegations as to SICOR, along with specific documented sources. *See* ¶¶ 319-24. Plaintiffs did not have to rely on "conclusory allegations" when the Chairman of the Commerce Committee determined that "[i]n 1998, a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare reimbursement was $141.97." ¶ 319. Moreover, Plaintiffs also cite a report published by DHHS wherein the DOJ documented at least 17 instances where published AWPs for SICOR drugs were grossly higher than the actual prices listed by wholesalers. ¶ 322. In order to further demonstrate SICOR's particular fraudulent conduct, Plaintiffs cite the 2001 AWPs SICOR reported to the *Red Book*, along with the much lower actual AWPs determined by the DOJ for the same drugs. ¶ 323.[14] In short, it is impossible to conceive of how SICOR can claim that Plaintiffs failed to plead the particular circumstances of SICOR's fraud.

Warrick, too, insists on pointing to fictional Rule 9(b) deficiencies in the MCC, despite ample particularized allegations regarding its AWP inflation scheme. Warrick asserts that its grossly inflated AWP for albuterol sulfate was merely its "sticker price" for that particular drug. Warrick Mtn. at 2. Warrick's argument is a sham. The plain meaning of the phrase "average wholesale price" does not and never has been defined as "sticker price." The only purpose served by inflating the AWPs (a/k/a Warrick's "sticker price") was to help Warrick increase sales by making it more profitable for providers to sell the Warrick albuterol sulfate. On its face, this kind of pricing scheme clearly gives rise to a strong inference of fraudulent intent. The inference is further substantiated by the fact that the DOJ determined the actual AWP for

[14] As an example, SICOR's 2001 *Red Book* AWP for the drug Tobramycin Sulfate was $342.19, and the DOJ determined the actual AWP for that same drug in the same dosage to be $6.98. MCC ¶ 323. The difference between the two AWPs created a 4,802% spread.

Warrick's albuterol sulfate to be $9.16, and Warrick's 2001 *Red Book* AWP for that same drug in the same dosage was $30.25, as indicated in the MCC. ¶ 317. Plaintiffs' allegations are further supported by letters from U.S. Rep. Tom Bliley, a GAO report to Congress detailing Warrick's conduct, ***and*** Warrick's own 2001 self-reported AWP, as published in the 2001 *Red Book*. ¶¶ 312-17. Accordingly, Plaintiffs meet the Rule 9(b) requirements standard with respect to Warrick.

While Immunex maintains that the MCC completely fails to allege fraud with the requisite particularity, the MCC specifically recounts fraudulent misrepresentations made directly by Immunex. ¶¶ 289-92. First, as fully described in the MCC, a spokeswoman from Immunex falsely stated that Immunex's AWPs are not its own; however, government-recovered internal documents exposed this fraud. ¶ 289. In a letter from *Red Book* to Immunex, a *Red Book* representative confirmed the "latest [Immunex] AWP price changes..." ¶ 289. This contradiction in itself indicates the fraudulent conduct. In addition, the MCC provides two examples of the gross spread between Immunex's 2001 *Red Book* AWPs and the DOJ-determined AWPs for the same drugs in the same dosages. ¶ 291. For example, Immunex's AWP for leucovorin calcium was $137.94, and the DOJ determined the same drug to have an AWP of $14.58. MCC ¶ 291. This 846% spread, if nothing else, clearly demonstrates the circumstances of the fraud in this case. In short, Immunex cannot hide behind fictional Rule 9(b) deficiencies.

III. PLAINTIFFS' STATE-LAW CLAIMS ARE NOT PREEMPTED

A. There Is No Medicare Act Preemption

In their reply brief, Defendants posit three arguments in favor of preemption by the Medicare Act. First, Defendants cite *Congress of Cal. Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 496 (2001), a California state court decision, for the proposition that there is no "presumption against preemption" in the field of Medicare drug reimbursement. (Defs. Reply at 16-17). However, *Catholic Healthcare* stands for no such proposition. In fact, the *Catholic*

Healthcare court ultimately concluded that, effectively, a presumption against preemption does exist, explaining that "the fact that public health is a field historically within the police powers of the states means the party asserting preemption must establish that preemption was the 'clear and manifest purpose of Congress.'" *Catholic Healthcare,* 87 Cal. App. 4th at 496. Furthermore, and as Plaintiffs argued in their opening brief, the First, Second and Third Circuits all have held that a presumption exists that Congress did not intend to displace state laws regulating public health, including the containment of medical costs. (*See* Plaintiffs' Opening Brief at 41.)

Next, Defendants cite *Catholic Healthcare* for the independent proposition that federal law comprehensively occupies the field of Medicare reimbursement. Defs. Reply Mem. at 17-18. Defendants' reliance is misplaced. In *Catholic Healthcare*, plaintiffs alleged that the defendant hospital committed an unlawful trade practice by including certain anti-union expenses in its annual Medicare cost reports in violation of Medicare Part A. *Id.* at 493.[15] After analyzing numerous regulations in the Provider Reimbursement Manual concerning reporting reasonable costs in relation to union activities, the court concluded that federal law comprehensively occupied the field of Medicare provider cost reporting and reimbursement practices. However, and as Plaintiffs argued in their opening brief (Plaintiffs' Opening Brief, p.43, n.31), *Catholic Healthcare* is distinguishable from the present case on several grounds. First, unlike in *Catholic Healthcare*, reimbursement (under Medicare Part A) based on the calculation and reporting of reasonable costs by providers is not at issue. Instead, Plaintiffs challenge the outside manufacturers' manipulation of a component upon which the providers' reimbursement is based. Here, there are no analogously comprehensive cost reporting regulations. In fact, the published AWPs are not even reviewed or approved by a government agency. Thus, Plaintiffs' state law claims will not require this Court to reexamine federal agency

[15] Part A relates only to services from institutional providers, whereas Part B is a voluntary program of supplementary medical insurance, generally reimbursing beneficiaries for part of the cost of certain doctors' services, x-rays, lab tests, and other medical services, including certain prescription drugs. *Id.* at 493-94.

rulemaking on the issue. Accordingly, federal law does not occupy the field and *Catholic Healthcare* is inapplicable.

Third, Defendants contend that Plaintiffs' state claims cannot be reconciled with BIPA's prohibition on "directly or indirectly' decreasing the rate of reimbursement" and therefore are a basis of conflict preemption. Defs. Reply Mem. at 18. To prevail, Defendants must show that Congress intended to shield fraud claims related to reimbursement under Medicare Part B from state regulation. *See Mass. Med. Soc'y. v. Dukakis,* 815 F.2d 790, 793-94 (1st Cir. 1987) (Defendants must show a "right immune from state regulation"); *Pennsylvania Med. Soc'y v. Marconis*, 942 F.2d 842, 857 (3d Cir. 1991) (no preemption without "clear and unequivocal indications of congressional intent or that [this is such] an integral part of the federal regulatory scheme that Congress intended to shield it from state supplementation."). However, as Plaintiffs argued at pages 43-44 of their opening brief, BIPA sanctions HCFA review and alteration of the AWP system; it does not prevent it. Moreover, requiring manufacturers to report accurate AWPs arguably does not alter the rate of reimbursement, but instead restores accuracy and financial integrity to the system that Congress intended.

B. There Is No ERISA Preemption

Defendants contend that Plaintiffs' state law claims are preempted by ERISA because "the Court will have to evaluate and interpret the terms of the ERISA plans to determine defendants' liability under the state law claims." Defs. Reply Mem. at 20. This argument lacks merit for two reasons.

First, ERISA preemption does not apply where, as here, Plaintiffs' state claims are against third-party non-fiduciaries to remedy fraud. Indeed, courts routinely allow common law fraud claims by ERISA plans or their trustees against non-fiduciaries to proceed without ERISA preemption. *See, e.g., LeBlanc v. Cahill*, 153 F.3d 134, 147 (4th Cir. 1998) (holding that Trustees' common law fraud claim was not preempted by ERISA because "[t]he fact that the Pension Fund is subject to ERISA is of no consequence to its common law fraud claim against

the Appellees. With respect to this claim, the Pension Fund is simply in the role of an investor allegedly wronged."); *Airparts Co. v. Custom Benefits/Servs.*, 28 F.3d 1062, 1066 (10th Cir. 1994) (holding that claims for malpractice and fraud against a nonfiduciary consultant were laws of general application and were not preempted by ERISA). Here, Plaintiffs are not suing the plan's trustees or fiduciaries – they are suing non-fiduciary drug companies for deceptive conduct and these claims cannot be preempted by ERISA.

Second, and even more importantly, the Court does not need to evaluate or interpret the terms of the ERISA Plan to determine liability. Here, Plaintiffs only assert claims under certain state consumer protection statutes. None of the consumer protection statutes expressly refers to ERISA plans. Moreover, the legal determination that the conduct of Defendants constitutes fraudulent practices does not require any resolution of any dispute or administration of the plan. *See Boston Children's Heart Found. v. Nadal-Ginard*, 73 F.3d 429, 440 (1st Cir. 1996). Nor are Plaintiffs required to prove the existence of or specific terms of the ERISA plan to establish their claims. That the deception is raised by the plans themselves is incidental and is not essential to plaintiffs' state claims. In short, because the Court's inquiry need not be directed to the ERISA Plan, Plaintiffs' state law claims are not preempted under ERISA.

IV. THE FILED RATE DOCTRINE DOES NOT BAR PLAINTIFFS' CLAIMS

Only two defendants, BMS and Braun contend that Plaintiffs' claims are barred under the filed-rate doctrine. However, the filed-rate doctrine is wholly inapplicable to the present case for several reasons.

First, and as Plaintiffs argued in their opening brief, the filed-rate doctrine does not extend to Medicare Part B drugs. Most decisions involving the filed-rate doctrine have involved heavily regulated industries, such as carriers or utilities, in which the law requires the filing of rates or tariffs. *See Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116, n.6 (D. Mass. 1998), *aff'd in part, rev'd in part on other grounds*, 202 F.3d 408 (1st Cir. 2000); *see*

also Taffet v. Southern Co., 967 F.2d 1483, 1488-90 (11th Cir. 1992) (surveying cases). Indeed, all of Defendants' cases fall into this category.

Defendants do not dispute that courts have not applied the filed rate doctrine to Medicare. BMS Reply Mem. at 5. This is not surprising since Medicare does not require rates to be filed. In addition, consideration of the doctrine's purposes reveals why an extension to Medicare is unwarranted. More specifically, no genuine public ratemaking process exists for Medicare covered drugs to trigger the filed-rate doctrine. The AWPs are set and reported to the publishers at the sole discretion of Defendants. Specifically, no government agency reviews or approves an AWP rate base or proper rate of return. Nor does any administrative mechanism exist to ensure that AWP rates are "just and reasonable," or even review the AWPs for accuracy. Accordingly, applying the filed-rate doctrine to Medicare Part B drugs would not serve the doctrine's purposes and only needlessly circumscribes the jurisdiction of the courts.

Next, despite Defendants' contention otherwise, Medicare has not established a rate that triggers the doctrine. Plaintiffs' opening brief demonstrated that AWPs cannot trigger the doctrine. As a result, Defendants creatively assert that Congress and HCFA have set so-called reimbursement rates which Defendants describe as "allowed amounts" used in calculating plaintiffs' co-payments. BMS Reply Mem. at 2; Braun Reply Mem. at 2. In short, Defendants appear to argue that the doctrine applies because Congress and HCFA mandate that Medicare payments be set at AWP. However, even if these so-called rates were the ones at issue rather than the AWPs, and they are not, such "allowed amounts" would be deemed void for purposes of applying the doctrine because they are based exclusively on AWPs set at the sole discretion of the manufacturer. As such, the so-called government rates have no fixed or predictable nature in the absence of Defendants' AWPs and are therefore rendered incomplete and meaningless. *See Atlantis Express, Inc. v. Associated Wholesale Grocers, Inc.*, 989 F.2d 281, 283 (8th Cir. 1993) (refusing to apply the filed rate doctrine where tariff was not effectively filed because it was incomplete and meaningless in the absence of distances to accompany distance rates). In sum,

the "rates" allegedly established by the government are based entirely on AWPs set at Defendants' sole discretion and therefore are meaningless for purposes of triggering the doctrine.[16]

Third, Defendants argue that the filed-rate doctrine should apply even though Medicare does not require rates to be filed. BMS Reply Mem. at 2; Braun Reply Mem. at 2. This argument is wrong. Indeed, Defendants concede that no rate has been filed here.[17] As Plaintiffs argued in their opening brief, the doctrine applies only after rates have been filed with the appropriate government agency. *See Town of Norwood v. New England Power Co.*, 202 F.3d 408, 416 (1st Cir. 2000).

In support of its argument that "rates" need not be filed, Braun asserts the principle that the filed rate doctrine is not limited to rates "per se." Braun Reply Mem. at 2. However, this point is of no consequence, because even in cases where rates are not directly at issue, the doctrine is only triggered where a plaintiff seeks relief that directly affects rates that were, in fact, previously filed with an agency. *See Natahala Power & Light Co. v. Thornburg*, 476 U.S. 953, 966-67 (1986).

Likewise, BMS cites two cases for the proposition that the filed rate doctrine applies where an agency created a formula without filing rates. BMS Reply Mem. at 4. However, these cases are easily distinguishable on their facts and only serve to bolster Plaintiffs' arguments. For example, in *Public Utilities Commission of the State of California v. Federal Energy Regulatory Commission*, 254 F.3d 250 (D.C. Cir. 2001), the court noted that the filed-rate doctrine was applicable there because the relevant government agency had a manner for ensuring "just and

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[16] Even if Plaintiffs' claims did involve an industry within the doctrine's traditional ambit, Plaintiffs have raised no claims of the kind that the filed-rate doctrine bars. Plaintiffs do not challenge the use of AWP by the government, but rather challenge Defendants' deliberate failure to publish accurate AWPs. *See Lipton v. MCI WorldCom, Inc.*, 135 F. Supp. 2d 182, 189 n.4 (D.D.C. 2001) (holding that filed tariff doctrine does not bar plaintiff's claim seeking to enforce the terms of the tariff).

[17] BMS, in a brief footnote, argues that a filing may have occurred when providers file claims that are reimbursed under Medicare rules. BMS Reply Mem. at 3, n.5. However, a provider's private filing for claims is not the equivalent of publicly filed rates that satisfy the doctrine's purpose of avoiding price discrimination between ratepayers.

reasonable rates" and the utility did not have unbridled discretion to set the rates ultimately charged. *Id.* at 255. Here, neither of these safeguards is in place to prevent Defendants from setting the alleged rates by manipulating AWPs at their discretion, as they did in fact do here. Similarly, in *Transmission Agency of N. Cal. v. Sierra Pac. Power Co.*, 287 F.3d 771 (9th Cir. 2002), the court emphasized that the operative order regulated rates "by setting rules requiring open access to transmission lines at ***uniform, openly disclosed, rates***.' *Id.* at 783 (emphasis added). Here, the manipulated AWPs do not constitute "uniform, openly disclosed rates." Accordingly, the filed rate doctrine is wholly inapplicable to this case.[18]

V. PLAINTIFFS' RESPONSE TO DISCREET ISSUES RAISED IN DEFENDANTS' INDIVIDUAL REPLY BRIEFS

A. Defendants' Manipulation Of The AWP For Multi-Source Drugs

In their individual reply memoranda Abbott, B. Braun, Warrick and other Defendants contend that all claims in the MCC should be dismissed to the extent that they relate to Medicare reimbursement for multi-source drugs. Defendants claim that they could not manipulate the AWP for competitive advantage with respect to multi-source drugs because Medicare's reimbursement for those drugs is based on the lower of the median of the AWP for all generic forms of the drug or the AWP for the corresponding named-brand drug. See Abbott Reply Mem. at 1. Defendants' arguments ignore reality.

First, as Defendants concede, the raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. See Abbot Reply Mem. at 2. This fact alone puts the publication and reporting of fraudulent AWPs by

[18] Defendant Braun wrongly contends that *Servais v. Kraft Foods, Inc.*, 631 N.W.2d 629 (Wis. Ct. App. 2001), applies here. *See* Brawn Reply Mem. at 2. In *Servais*, the Wisconsin state court based its decision on the fact that the Department of Agriculture studied, reviewed and held public hearings on rates before issuing its formal approval in the form of a recommendation. *Id.* at 632-33. Here, however, the purported "rates" are based on AWPs set at the discretion of Defendatns without any review or approval by the federal government. Thus, *Servais* is inapposite.

Defendants for generic drugs squarely within the activity complained of in the MCC. Second, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

Documents produced to Plaintiffs since the filing of the MCC clearly indicate that generic manufacturers are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples from the MCC are excerpted below:

Defendant	**Multisource Drug**	***RedBook* AWP**	**DOJ Determined Actual AWP**	**Spread**	**MCC Reference**
Abbott	Sodium Chloride	$670.89	$3.22	20,735%	¶190
Baxter	Dextrose	$928.51	$2.25	41,167%	¶217
Baxter	Sodium Chloride	$928.51	$1.71	54,199%	¶217
Boehringer Group	Leucovorin Calcium	$184.40	$2.76	6,581%	¶231
B. Braun	Sodium Chloride	$11.33	$1.49	660%	¶235
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%	¶238
Dey	Albuterol Sulfate	$30.25	$9.17	230%	¶251
Immunex	Leucovorin Calcium	$137.94	$14.58	846%	¶291
Pharmacia	Etoposide	$157.65	$9.47	1,565%	¶306

Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%	¶323
Watson	Vancomycin HCL	$70.00	$3.84	1,567%	¶327

Defendants' contention that Plaintiffs' claims cannot, as a matter of law, apply to the reporting of AWPs for generic or multi-source drugs ignores the facts. Multi-source drugs are subject to fraudulent AWP manipulation as set forth in the MCC.

B. The Juridical Link Between Defendants

In their individual briefs, Baxter, B. Braun, Bayer and Sicor each challenge the standing of Plaintiffs to bring suit against each Defendant. These Defendants claim that there can be no juridical link between Defendants because there is not a "contractual, corporate or legal link" between Defendants sufficient enough to find a juridical link between them. See Baxter Reply Mem. at p. 2. However, given the facts as set forth in the MCC, the link between Defendants is more than sufficient to find a juridical link to establish standing on behalf of each Plaintiff as against Defendants for which a particular Plaintiff may not have purchased a drug.

As Sicor in its brief has conceded, the juridical link doctrine applies where "conduct is standardized by a common link to an agreement, contract *or enforced system which acts to standardize the underpinnings of the claims*." *Angel Music v. ABC Sports, Inc.* 112 F.R.D. 70, 72 (S.D.N.Y. 1986) (emphasis added) See Sicor Reply Mem. at p. 2. In the instant case there exists an enforced system, namely the Medicare regulations which set reimbursement at 95% of the AWP, to which all Defendants adhere and which operates to standardized the claims set forth in the MCC. The enforced system for Medicare reimbursement and Defendants' perversion of

this system though the reporting of fraudulent AWPs underpin each of the claims set forth in the MCC. This standard statutory scheme is sufficient to allow a finding of juridical linkage.

In addition, the application of the concept of juridical linkage has recently been approved in a context quite analogous to the instant case. Most notably, in *Weld v. Glaxo Wellcome Inc.*, 434 Mass. 81, 91 (2001), the Massachusetts Supreme Judicial Court found that the plaintiffs had standing to sue pharmaceutical companies with whom they had no connection because the companies used the same agent to distribute letters as the pharmaceutical companies with whom the plaintiffs did have a connection. There, the court stated:

> Although the contracts between CVS and the pharmaceuticals appear to have been the product of independent, parallel negotiations, every contract created largely identical contractual obligations between CVS and the pharmaceuticals, and the program appears to have been administered in a substantially similar manner across the board. Each pharmaceutical provided financing, selection criteria, and letter content in exchange for CVS's promise to send letters on its letterhead to its customers who satisfied those criteria. The pharmaceuticals' contractual obligations to CVS were directly and exclusively related to the single course of conduct about which Kelley complains. Kelley's claims are typical because he and the members of the class shared a common relationship with CVS as pharmacy customers who were made unwitting participants in the program, and the pharmaceuticals are juridically linked through their contracts with CVS and participation as sponsors of the program.
>
> *Weld v. Glaxo Wellcome Inc.*, 434 Mass. 81, 91 (2001).

As in *Weld*, Defendants here have engaged in a single course of conduct about which each Plaintiff complains – the unlawful inflation of the AWP for their products. ¶¶ 183-328. As in *Weld*, each Defendant used the same agent or agents, namely the *Redbook*, *Blue Book* and *Medi-Span* to accomplish their unlawful ends and disseminate their fraudulently inflated AWPs. ¶¶ 134-135. Each Defendant also perverted a uniform statutory regimen to accomplish its unlawful goal - the system set up by Congress for determining reimbursement under Medicare Part B for their products. ¶¶136-139. These alleged facts must be taken to be true for our purposes, *Warth v. Seldin*, 422 U.S. 490, 501 (1975), which can only lead to the conclusion that

Defendants are juridically linked to one another. Consequently, Plaintiffs have standing to assert claims against Defendants from which they may not have purchased a drug because of the juridical relationship between Defendants. Plaintiffs need not allege dealings with each Defendant to establish standing against each Defendant.

C. Plaintiffs' Individual Standing

In their Consolidated Memorandum in Opposition to Defendants Motions to Dismiss, Plaintiffs submitted affidavits from each of the organizational Plaintiffs as well as from three of the four health and welfare fund Plaintiffs in support of Plaintiffs' standing. In further support of the arguments set forth in its Consolidated Opposition, Plaintiffs also hereby submits the Declaration of William J. Einhorn, Administrator of Teamsters Health and Welfare Fund of Philadelphia and Vicinity attached hereto as Exhibit A.

VI. CONCLUSION

For the foregoing reasons, and for the reasons set forth in Plaintiffs' Consolidated Opposition to Defendants' Motions to Dismiss, Defendants' motions should be denied.

By _____ DATED: January 8, 2003.

Thomas M. Sobol (BBO# 471770)
Edward Notargiacomo (BBO# 567636)
Hagens Berman LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

LIAISON COUNSEL

Steve W. Berman
Sean R. Matt
Kevin P. Roddy
Hagens Berman LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Samuel Heins
Heins, Mills & Olson, P.C.
700 Northstar East
608 Second Avenue South
Minneapolis, MN 55402
Telephone: (612) 338-4605
Facsimile: (612) 338-4692

Eugene A. Spector
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

CHAIRS OF LEAD COUNSEL COMMITTEE

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Kenneth A. Wexler
Elizabeth Fegan Hartweg
Kenneth A. Wexler & Associates
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

MEMBERS OF LEAD COUNSEL COMMITTEE AND EXECUTIVE COMMITTEE

Michael McShane
Alexander, Hawes & Audet, LLP
300 Montgomery Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 982-1886
Facsimile: (415) 576-1776

Robert E. Piper, Jr.
Piper & Associates
624 Pierre Avenue
Shreveport, LA 71103
Telephone: (318) 226-0826
Facsimile: (318) 424-9900

MEMBERS OF EXECUTIVE COMMITTEE

Anthony Bolognese
Bolognese & Associates
One Penn Center
1617 JFK Boulevard
Suite 650
Philadelphia, PA 19103
Tel: (215) 814-6750
Fax: (215) 814-6764

Michael J. Flannery
Carey & Danis, LLC
676 North Michigan Ave.
Suite 3110
Chicago, IL 60611
Tel: (312) 649-0100
Fax: (312) 664-7731

Jonathan W. Cuneo
The Cuneo Law Group
317 Massachusetts Avenue, N.E.
Suite 300
Washington, D.C. 20002
Tel: (202) 789-3960
Fax: (202) 789-1813

Neal Goldstein (Of Counsel)
Freedman & Lorry, PC
400 Market Street, Suit 900
Philadelphia, PA 19106
Tel: (215) 925-8400

Tel: (213) 895-6500
Fax: (213) 895-6161

Jonathan Shub
Sheller, Ludwig & Badey, P.C.
1528 Walnut Street, 3rd fl
Philadelphia, PA 19102
Tel: (215) 790-7300
Fax: (215) 546-0942

Scott R. Shepherd
Shepherd & Finkleman, LLC
117 Gayley Street,
Suite 200
Media, PA 19063
Tel: (610) 891-9880
Fax: (610) 891-9883

Lee Squitieri
Squitieri & Fearon
521 Fifth Avenue, 26th floor
New York, NY 10175
Tel: (646) 487-3049
Fax: (646) 487-3095

Lisa J. Rodriguez
Ira Neil Richards
Trujillo Rodriguez& Richards, LLC
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Tel: (215) 731-9004
Fax: (215) 731-9044

Mitchell A. Toups
Weller, Green, Toups & Terrell, L.L.P.
2615 Calder Street, Suite 400
P.O. Box 350
Beaumont, TX 77704
Tel: (409) 838-0101
Fax: 409-838-6780

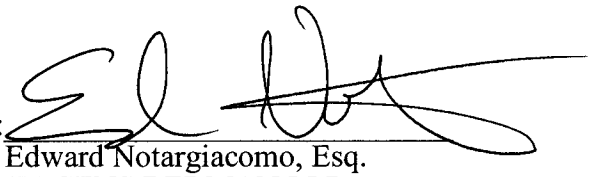
Damon Young
Lance Lee
Young, Pickett & Lee
4122 Texas Boulevard

P.O. Box 1897
Texarkana, AR/TX 75504
Tel: (903) 794-1303
Fax: 903-792-5098; 903-794-5098

ADDITIONAL ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Sur-Reply To Defendants' Consolidated Motion To Dismiss to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2.

By: 

Edward Notargiacomo, Esq.
HAGENS BERMAN LLP
225 Franklin Street, 26th floor
Boston, MA 02110
(617) 482-3700